Attorney Docket: 763-29

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPLICANT:	Yoshio Jo et al.	**EXAMINER:** Oh, Simon J.	
SERIAL NO.:	10/069,561	**GROUP ART UNIT:** 1615	
FILED:	October 22, 2001	**DATED:** November 29, 2004	
FOR:	**SOLUBLE TRAUMA-HEALING HEMOSTATIC CELLULOSE CONTAINING COAGULATION PROTEIN AND METHOD OF PREPARATION THEREOF**		

Mail Stop Appeal Brief-Patents
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' BRIEF

Sir:

(1) REAL PARTY IN INTEREST

The real party in interest is Hogy Medical Co., Ltd having an office at 12-4, Yushima 1-Chome, Bunkyo-ku, Tokyo, Japan, the assignee of the subject application.

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this Appellants' Brief in triplicate is being deposited with the United States Postal Service as first class mail, postpaid in an envelope addressed to the: Mail Stop Appeal Brief-Patents, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 29, 2004.

Dated: November 29, 2004

George M. Kaplan

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(2) RELATED APPEALS AND INTERFERENCES

To the best of appellants' knowledge and belief, there are no related appeals or interferences.

(3) STATUS OF CLAIMS

Of Claims 1-74, Claims 1-33, 35, 56 and 63 have been cancelled without prejudice.

Claims 34, 36-55, 57-60 and 62-74, stand finally rejected and constitute the claims on appeal. A copy of the appealed claims is contained in the Claims Appendix.

(4) STATUS OF AMENDMENTS

There has been no amendment filed subsequent to the final rejection set forth in the Office Action mailed January 27, 2004.

(5) SUMMARY OF CLAIMED SUBJECT MATTER

The appealed claims are directed to distinct and important improvement in manufacturing a soluble trauma-healing hemostatic cellulose fiber containing coagulation proteins and which rapidly dissolves when contacting blood to provide excellent hemostatic effect, especially in a large amount of blood such as a wound (Claims 34, 36-55, 57-60 and 62-74).

Furthermore, the inventive hemostatic fiber enhances adhesion and aggregation of blood platelets at the wound and interacts with fibronectin which is an adhesion protein, to

promote cell adhesion activity of the fibronectin. The claimed hemostatic fiber is based on this finding.

The claimed hemostatic fiber having excellent absorption and dissolution includes a natural or regenerated cellulose fiber that has been partially carboxymethylated to an extent such that degree of substitution of the hydroxyl groups in the glucose units constituting the cellulose molecule is 0.5- less than 1.0.

Three specific types of coagulation proteins, namely fibrinogen, thrombin and coagulation factor XIII, are applied or chemically bonded to the fiber followed by drying. Therefore, the fiber possesses activity for accelerating a coagulation reaction of fibrin monomers converted from fibrinogen with thrombin and possesses activity for stabilizing agglutinates by cross-linking reaction with the coagulation factor XIII (independent Claim 34).

The claimed method of producing a soluble trauma-healing hemostatic cellulose fiber includes the steps of

treating a natural or regenerated cellulose fiber with an aqueous sodium hydroxide solution,

reacting the thus-treated fiber with a monochloro acetic acid solution for carboxymethylation to an extent such that degree of substitution of hydroxyl groups of the glucose units constituting the cellulose molecule (etherification degree) is 0.5 to less than 1.0,

subsequently refining the fiber and then imparting or chemical bonding the three specific coagulation proteins, namely fibrinogen, thrombin and coagulation factor XIII, to the refined cellulose fiber, and

then drying the fiber.

The thus-produced fiber possesses activity for accelerating coagulation reaction of fibrin monomers converted from fibrinogin with thrombin, and possesses activity for stabilizing the agglutinates by the cross-linking reaction with coagulation factor XIII (independent Claim 53).

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 34, 36-55, 57-60 and 62-74 stand rejected under 35 U.S.C. §103(a) as being obvious over European Pat. Pub. No. 0 956 869 to Soe et al. (hereinafter "EP '869") in view of U.S. Pat. No. 4,340,731 to Columbo et al. (hereinafter "Columbo et al."), U.S. Pat. No. 5,962,026 to Edwardson et al. (hereinafter "Edwardson et al.") and U.S. Pat. No. 4,265,233 to Sugitachi et al. (hereinafter "Sugitachi et al.").

(7) ARGUMENT

(A) THE COMBINATION OF REFERENCES FASHIONED IN THE FINAL REJECTION FAILS TO ESTABLISH A CASE OF PRIMA FACIE OBVIOUSNESS

As enunciated in M.P.E.P. §2142, to establish a *prima facie* case of obviousness,

(1) some suggestion or motivation to combine or modify the reference teachings must exist,

(2) there must be a reasonable expectation of success, and

(3) the references, in combination, must teach or suggest all the claim limitations.

Applicants' disclosure cannot be used to remedy any deficiencies in requirements (1)-(3) *supra.*

EP '869 fails to disclose a hemostatic fiber. Columbo et al merely relate to etherification of cellulose fibers ultimately used in products such as sanitary towels or napkins, bandages, tampons, etc. (column 7, lines 1-2); there is no suggestion in this reference of utilizing the fibers for wound healing benefit. Edwardson et al just contain a general disclosure that a thrombin-like enzyme can be immobilized upon a support such as cellulose or derivatives; there is no explicit teaching in Edwardson et al of preparing an etherified cellulose fiber as in the claimed invention with the coagulation proteins imparted in the inventive fashion.

Finally, Sugitachi et al merely disclose fixing blood coagulation factor XIII to a variety of structures such as sutures, pads, bandages, etc. formed from a variety of materials, such as carboxymethycellulose (column 1, line 49- column 2, line 5). There is no explicit suggestion in Sugitachi et al of preparing the claimed etherified cellulose fiber with all three coagulation proteins imparted thereto. The structures of Columbo et al and Sugitachi et al are not designed for dissolution as claimed.

Therefore, the combination of all four of these references fails to teach or suggest a trauma-healing hemostatic cellulose fiber being partially carboxymethylated and comprising three particular types of coagulation proteins applied or chemically bonded thereto. Moreover, motivation to combine the four references and reasonable chance of success have

not been established. Accordingly, these four references, in combination fail to establish a *prima facie* case of obviousness of the claimed invention.

(B) RELIANCE UPON FOUR REFERENCES TO FASHION THE REJECTION WEIGHS AGAINST OBVIOUSNESS OF THE CLAIMED INVENTION

In the Response to Arguments on page 5 of the Final Office Action, it is stated

> In response to applicant's argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention . . . *In re Gorman,* 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991)[emphasis added]

However, it is explicitly stated in the *Gorman* decision cited by the Examiner, the degree to which a large number of references may be successfully combined to fashion an obviousness rejection, must be decided upon the facts of each case. In this regard, it is explicitly stated by the Court in *Gorman*

> It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.[citations omitted] The references themselves must provide some teaching whereby the applicant's combination would have been obvious (18 USPQ2d at 1888, column 2)[emphasis added]

In the present instance, Appellants' argument on the large number of references being combined is not being made in isolated context. Rather, when considered in conjunction with the other arguments and evidence set forth *infra*, it is quite clear the large number of references resorted to by the Examiner most certainly helps substantiate the unobviousness of the claimed invention over the combination of art being applied herein. In

other words, Appellants have indeed provided "more" to weigh against the obviousness assertion by the Examiner, as even required by the Examiner on page 5 of the Final Office Action.

(C) THE COMBINATION OF EP '869 WITH COLUMBO ET AL, EDWARDSON ET AL AND SUGITACHI ET AL CONSTITUTES IMPROPER HINDSIGHT RECONSTRUCTION OF THE CLAIMED INVENTION IN LIGHT OF THE INVENTION DISCLOSURE FOUND IN THE PRESENT APPLICATION

In the Response to Arguments on pages 5-6 of the Final Office Action, it is stated

> In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper.. .*In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971) [emphasis added].

However, the Court in *McLaughlin* then explicitly stated

> The forgoing conclusion in itself, however, is not determinative of the present appeal. Appellant has submitted evidence tending to prove that his invention has solved the longstanding problem. . . (170 USPQ at 212, column 2) [emphasis added]

In the present instance, evidence has also been submitted and will be discussed *infra*. However, attention is called to the quote from the *Gorman* decision set forth *supra* (a more recent decision), and which forbids merely selecting elements from individual references and then using Applicants' disclosure as a guide for combining such isolated elements in the manner of the claimed invention.

In the present instance, EP '869 fails to disclose a hemostatic fiber; Columbo et al merely relate to etherification of cellulose fibers ultimately used in products such as sanitary towels or napkins, bandages, tampons, etc., there being no suggestion of providing wound healing benefit; Edwardson et al just contain a general disclosure a thrombin-like enzyme can be immobilized upon a support such as cellulose or derivatives, there being no explicit teaching of preparing an etherified cellulose fiber with the coagulation protein combination as recited in the claimed invention; and Sugitachi et al merely disclose fixing blood coagulation factor XIII to a variety of structures such as sutures, pads, bandages, etc.

Thus, there is no explicit suggestion in Sugitachi et al, or any of the other references, of preparing the claimed cellulose fiber with all three coagulation proteins in combination. The structures of Columbo et al and Sugitachi et al are not designed for dissolution as claimed. That is why Applicants have pointed out the disclosures of the various references show products such as bandages, pads, and sutures, as questioned by the Examiner on page 6 of the Final Office Action.

Therefore, it is quite clear the only suggestion of preparing a soluble, trauma-healing hemostatic fiber in the fashion of the claimed invention is found in the disclosure of the present application. Accordingly, the combination of references being fashioned in the Final Office Action constitutes nothing more than using Applicants' disclosure as a template to effect an obviousness rejection and impermissible hindsight reconstruction of the claimed invention in light of the standards set forth in the *Gorman* decision quoted *supra*.

(D) THE CLAIMED INVENTION IS NOT INHERENTLY SHOWN BY THE PRIOR ART

It is stated at the top of page 5 of the Final Office Action:

> [T]he features embodied in the Claims 67-74, fibrinomer absorptivity, maximum platelet agglutination rate, agglutination percentage, adhered cell count, and mean hemostatis time, would be inherent to the disclosure of the prior art [emphasis added].

It is pointed out inherency must be absolutely certain and not a mere possibility: In re Oelrich (CCPA 1981) 666 F.2d 578, 212 USPQ 323; Ex part Keith et al. (POBA 1966) 154 USPQ 320. As was stated in the CCPA decision Hansgirg v. Kimmer (CCPA 1939) 102 F.2d 212, 40 USPQ 665 more than 60 years ago:

> Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient [emphasis added].

Further, it is explicitly stated in M.P.E.P. §2112 (IV) the Examiner must provide rationale or evidence tending to show inherency. The fact the Examiner has resorted to a combination of four references clearly substantiates the claimed features are not inherently disclosed in any one of these four references which could, *arguendo*, be combined in any of a variety of possible fashions.

Furthermore, attention is respectfully called to an article written by Irving N. Feit and Christina L. Warrick entitled "Inherency in Patent Law" in the January 2003 issue of the Journal of the Patent and Trademark Office Society (JPTOS vol. 85, no. 1, January 2003, pp. 5-21) (copy attached in (10) Evidence Appendix). The following conclusion is posited by the authors on page 21 (the last page) of this article:

> The authors believe all of the cases described above, [case citations deleted] can be reconciled. The cases appear to be consistent with the proposition that the ultimate standard for determining whether a claimed element is inherent in the prior art is the objective understanding of a person having ordinary skill in the art [emphasis added].

That objective understanding has been clearly set forth in the Declaration executed by joint inventor Yoshio Jo and discussed *infra*.

(E) EVIDENCE AND ARGUMENTS CONTAINED IN THE DECLARATION UNDER 37 C.F.R. §1.132 BY JOINT INVENTOR YOSHIO JO REBUTS ANY PRIMA FACIE PRESUMPTION OF OBVIOUSNESS OF THE CLAIMED INVENTION

It is asserted towards the end of page 6 of the Final Office Action, the burden has been shifted to Appellants to clearly distinguish between what is claimed from what is disclosed collectively in the prior art. Even assuming, *arguendo*, a *prima facie* case of obviousness of the claimed invention over the cited art has been made by the Examiner, nevertheless the Declaration under 37 C.F.R. §1.132 from joint inventor Yoshio Jo clearly rebuts any such presumption for the following reasons.

In paragraph 3 of his Declaration, Mr. Jo states the present invention provides distinct, important improvement in manufacturing a soluble, trauma-healing hemostatic cellulose fiber containing (three types of) coagulation proteins and which rapidly dissolves when contacting blood to provide excellent hemostatic effect. Three examples (1)-(3) of the manner of activity of the inventive fiber are set forth in paragraph 3 of his Declaration, with other properties also set forth in paragraph 4 thereof.

It is explicitly stated by Mr. Jo in paragraph 5 of his Declaration the testing set forth in the Tables and Figures of the present application was carried out under his direction and control. This testing is explicitly addressed in paragraphs 6-11 of his Declaration. To summarize, degree of hydroxyl group substitution is effectively controlled in the inventive fiber, which is then completely soluble in water and saline. Improved fibrin monomer

absorptivity, platelet agglutination activity, adhered cell count and reduced hemostasis time is attained with the inventive fiber over hemostatic fiber containing no protein or the total absence of fiber altogether.

More particularly, the test results presented in Table 1 found at the bottom of page 9 of the present application document ability to control degree of hydroxyl group substitution in the hemostatic cellulose fiber, namely by controlling reaction time with monochloro acetic acid in accordance with the inventive method of preparation. The results reported in Table 2 found at the top of page 12 of the specification document complete solubility of the inventive hemostatic cellulose fiber in water and saline, whether the coagulation protein is imparted to the fiber by spraying or chemical bonding. Test results presented in Fig. 1 show the substantial improvement in fibrinomer absorptivity with the inventive hemostatic fiber having the coagulation protein either applied to the surface thereof or chemically bonded thereto (graphs C and D); thus, the methods of application clearly result in a different improved hemostatic fiber being obtained and are not mere processing limitations.

The results presented in Table 3 on page 14 of the present application and illustrated in Fig 2 document improved platelet agglutination activity provided by the inventive hemostatic fiber. Table 4 at the top of page 16 documents greatly improved adhered cell count with the inventive fiber. Test results documented in Table 5 at the top of page 18 of the specification show hemostasis can be achieved with the inventive fiber in as little as 10-11 seconds.

Therefore, the testing set forth in the present application compares the closest prior art to the claimed invention. In fact, hemostatic fiber containing no protein failed to improve platelet agglutination over the total absence of hemostatic fiber altogether. If anything, one

skilled in the art would be lead away from even looking to such fiber to improve hemostasis, hence away from the invention claimed herein. Accordingly, Mr. Jo concludes, in paragraph 12 of his Declaration, the improvements documented by this testing are surprising to him and not at all expected by the level of skill in the art available to him.

Mr. Jo then addresses the individual references in paragraphs 14-17 of his Declaration. Firstly, Mr. Jo points out in paragraph 14 EP '869 fails to show preparation of a cellulose fiber, much less a fiber imparted with the coagulation proteins in the manner of the present invention. The Examiner has even acknowledged at the top of page 3 of the Final Office Action, EP '869 fails to teach a fiber hydroxylated to the degree claimed and combined with coagulation proteins in the manner of the claimed invention.

Mr. Jo then points out in paragraph 15 Colombo et al prepare hydroinsoluble carboxy-alkyl cellulose for use in towels, napkins, bandages, etc., thus clearly leading away from the presently claimed invention and documented improvements. By the same token, Mr. Jo points out, in paragraph 17, Sugitachi et al also disclose fixing a blood coagulation factor to sutures, pads, bandages, etc. which are also not intended to be water-soluble, hence also teaching away from the claimed invention.

Edwardson et al are dismissed by Mr. Jo in paragraph 16 of his Declaration. In this regard, Mr. Jo points out none of these applied references teaches or suggests preparing the inventive fiber with the combination of all three coagulation proteins as claimed. Therefore, Mr. Jo concludes, in paragraph 18 of his Declaration, even if the teachings of all four references are combined, such a combined teaching still fails to suggest to him, one skilled in the art, the surprising advantages attained by the claimed invention as documented in the testing set forth in the present application.

(F) DEPENDENT CLAIMS 36-52, 54, 55, 57-60 and 62-74 ALSO RECITE PATENTABLE SUBJECT MATTER OVER THE APPLIED ART.

EP '869, Columbo et al., Edwardson et al. and Sugitachi et al. all fail to disclose the fiber having the coagulation proteins either applied by spraying to the surface thereof or chemically bonded thereto set forth in Claims 36-40, 42, 43 and 46. In this regard, it is pointed out the results reported in Table 2 found at the top of page 12 of the specification document complete solubility of the inventive hemostatic cellulose fiber in water and saline, whether the coagulation proteins are imparted to the fiber by spraying or chemical bonding. Test results presented in Fig. 1 show the substantial improvement in fibrinomer absorptivity with the inventive hemostatic fiber having the coagulation proteins either applied to the surface thereof or chemically bonded thereto (graphs C and D); thus, the methods of application as recited in Claims 36-40, 42, 43 and 46 clearly result in a different improved hemostatic fiber being obtained.

The pulverization treatments recited in Claims 44, 45 and 47 are not disclosed in any of these references. More particularly, Sugitachi et al merely disclose fixing blood coagulation factor XIII to a variety of structures such as sutures, pads, bandages, etc. formed from a variety of materials, such as carboxymethycellulose (column 1, line 49- column 2, line 5). There is no explicit suggestion in Sugitachi et al of preparing the claimed etherified cellulose fiber with all three coagulation proteins imparted thereto. The structures of Columbo et al and Sugitachi et al are not designed for dissolution where the claimed fibers can be pulverized before hemostatic application as recited in Claims 44, 45 and 47.

By the same token, the specific processing parameters recited in Claims 54, 55 and

57-66 which result in the improved, wound-healing hemostatic fiber as documented in the present application, are not suggested by the applied art, even in combination. Preparation of a soluble fiber, fabric or gauze-like material as recited in Claims 49-52 imparting effective wound-healing benefit, is neither taught nor suggested by the applied art, even in combination. For example, there is no suggestion of the fibers having the specific denier recited in Claim 51 or intertwining recited in Claims 49 and 50. Claims 67-74 have been addressed under Argument 7(D) *supra*. Edwardson et al fail to disclose treating the claimed fiber with carbodiimide prior to reaction with the claimed protein combination, hence fail to suggest the invention recited in Claims 41 and 48 is obvious.

All of the features recited in the dependent claims result in the advantageous improvements well-documented in the present application and accompanying Declaration from joint inventor Yoshio Jo. Therefore, these claims are each individually patentable over the combination of art being applied.

(8) CONCLUSION

For the forgoing reasons and all reasons of record, it is submitted appealed Claims 34, 36-55, 57-60 and 62-74 are patentable over the prior art relied upon by the Examiner. Accordingly, reversal of the final rejection of all claims by the Board is believed to be warranted and respectfully requested.

Respectfully submitted,

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(9) CLAIMS APPENDIX

Appealed Claims 34, 36-55, 57-60 and 62-74 are as follows:

34. A soluble trauma-healing hemostatic cellulose fiber, comprising a natural or regenerated cellulose fiber that has been partially carboxymethylated to an extent such that degree of substitution of the hydroxyl groups in the glucose units constituting the cellulose molecule is 0.5- less than 1.0,

wherein three types of coagulation proteins being fibrinogen, thrombin and coagulation factor XIII are applied or chemically bonded to said fiber followed by drying,

such that said fiber possesses activity for accelerating a coagulation reaction of fibrin monomers converted from fibrinogen with thrombin and possesses activity for stabilizing agglutinates by cross-linking reaction with the coagulation factor XIII.

36. The fiber of claim 34, wherein the coagulation protein is imparted by surface application to the carboxymethylated natural or regenerated cellulose fiber.

37. The fiber of claim 36, wherein the coagulation protein is applied by spraying a solution thereof onto the fiber.

38. The fiber of claim 36, wherein a mixture of all three proteins is imparted in a single application.

39. The fiber of claim 36, wherein said three proteins are consecutively imparted in individual applications.

40. The fiber of claim 34, wherein said protein is imparted by chemical bonding to the carboxymethylated natural or regenerated cellulose fiber.

41. The fiber of claim 40, wherein said fiber is treated with carbodiimide prior to the reaction with the protein.

42 . The fiber of claim 40, wherein a mixture of all three proteins is chemically bonded in a single pass.

43. The fiber of claim 40, wherein said three proteins are chemically bonded in consecutive passes.

44. The fiber of claim 34, wherein the fiber is pulverized after the protein is imparted.

45. The fiber of claim 39, wherein a plurality of said thus-treated fibers are individually pulverized and then mixed.

46. The fiber of claim 45, wherein the proteins are applied by spraying solutions thereof.

47. The fiber of claim 43, wherein a plurality of said thus-treated fibers are individually pulverized and then mixed.

48. The fiber of claim 47, wherein the fibers are treated with carbodiimide reagent prior to the chemical reaction.

49. A drawn thread array having a number of single threads of the fiber according to claim 34 loosely twisted together.

50. A woven fabric comprising a plain or twill woven array of claim 49.

51. The fabric of claim 50, wherein the arrays of the drawn fibers have a thickness of 20-100 Denier.

52. Gauze-like material obtained by shoddy wool treatment of fibers of claim 34.

53. A method of producing a soluble trauma-healing hemostatic cellulose fiber, comprising the steps of:

treating a natural or regenerated cellulose fiber with an aqueous sodium hydroxide

solution,

reacting the thus-treated fiber with a monochloro acetic acid solution for carboxymethylation to an extent such that degree of substitution of hydroxyl groups of the glucose units constituting the cellulose molecule (etherification degree) is 0.5 to less than 1.0,

subsequently refining the fiber and then imparting or chemical bonding three coagulation proteins which are fibrinogen, thrombin and coagulation factor XIII, to the refined cellulose fiber, and

then drying the fiber,

whereby said fiber possesses activity for accelerating a coagulation reactionof fibrin monomers converted from fibrinogin with thrombin, and possesses activity for stabilizing the agglutinates by the cross-linking reaction with the coagulation factor XIII.

54. The method of claim 53, wherein the proteins are imparted by spraying a solution of all three proteins in a single pass.

55. The method of claim 53, wherein the proteins are imparted by spraying respective solutions of each said protein in consecutive passes.

57. The method of claim 53, wherein the proteins are imparted by chemical bonding with a single solution of all three proteins in a single pass.

58. The method of claim 53, wherein the proteins are imparted by chemical bonding with respective solutions of each said protein in consecutive passes.

59. The method of claim 53, comprising the additional step of pulverizing the fiber after drying.

60. The method of claim 55, comprising the additional step of after drying,

pulverizing and then mixing thus-produced fibers.

62. The method of claim 53, wherein the reaction with monochloro acetic acid is carried out for 4-18 hours.

63. The method of claim 53, comprising the additional step of loosely twisting threads of said fiber together to form a drawn thread array.

64. The method of claim 63, comprising the additional step of plain or twill weaving the drawn thread array to form a woven fabric.

65. The method of claim 63, wherein the drawn fiber array is formed with a thickness of 20-100 Denier.

66. The method of claim 53, comprising the additional step of carrying out shoddy wool treatment of the fibers to form a gauze-like material.

67. The fiber of claim 37 possessing fibrinomer absorptivity at 350 nm of at least 0.4 after 3 minutes of application.

68. The fiber of claim 40 possessing fibrinomer absorptivity at 350 nm of at least 0.4 after 3 minutes of application.

69. The fiber of claim 37 possessing a maximum platelet agglutination rate of at least about 94% and an agglutination % 1 minute after addition of at least about 92%.

70. The fiber of claim 40 possessing a maximum platelet agglutination rate of at least about 94% and an agglutination % 1minute after addition of at least about 92%.

71. The fiber of claim 37 possessing an adhered cell count for fibronectin, vitronectin, laminin, collagen or fibrin of at least about 285 after 6 hours of application.

72. The fiber of claim 40 possessing an adhered cell count for fibronectin, vitronectin, laminin, collagen or fibrin of at least about 285 after 6 hours of application.

73. The fiber of claim 37, possessing a mean hemostasis time of about 10-11 seconds after application to an approximately 1 square cm. trauma site in livers of rats.

74. The fiber of claim 40, possessing a mean hemostasis time of about 10-11 seconds after application to an approximately 1 square cm. trauma site in livers of rats.

(10) EVIDENCE APPENDIX

Copy of Declaration from joint inventor Yoshio Jo executed May 26, 2004 (Jo Declaration).

Copy of article written by Irving N. Feit and Christina L. Warrick entitled "Inherency in Patent Law" in the January 2003 issue of the Journal of the Patent and Trademark Office Society (JPTOS vol. 85, no. 1, January 2003, pp. 5-21).

Attorney Docket No.: 763-29 (PCT-01-001US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Yoshio Jo, et al. Group Art Unit: 1615

Serial No: 10/069,561 Examiner: Oh, Simon J.

Filed: October 22, 2001 Dated: May 19, 2004

For: **SOLUBLE TRAUMA-HEALING HEMOSTATIC CELLULOSE**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION

I, Yoshio Jo, do hereby declare:

1. I am one of the joint inventors of the invention being claimed in the above-identified patent application;

2. I have read and understand the Office Action mailed January 27, 2004 by the Patent and Trademark Office in the above-identified application and the art being applied therein, namely European Pat. Appln. No. 0956869 (an equivalent to U.S. Pat. No. 6,200,587 to Soe et al.), U.S. Pat. No. 4,340,731 to Colombo et al., U.S. Pat. No. 5,962,026 to Edwardson et al. and U.S. Pat. No. 4,265,233 to Sugitachi et al. (hereinafter referred to as "Soe et al.", "Colombo et al.", "Edwardson et al." and "Sugitachi et al.");

3. The present invention, provides distinct and important improvement in manufacturing a soluble trauma-healing hemostatic cellulose fiber containing coagulation

proteins and which rapidly dissolves when contacting blood to provide excellent hemostatic effect, especially in a large amount of blood such as a wound. More particularly, the claimed hemostatic fiber exhibits the important hemostatic effect in the following manner:

(1) The cellulose fiber possesses excellent absorption by tissue fluid such as blood and rapidly dissolves when contacting the blood;

(2) The cellulose fiber accelerates coagulation reaction of fibrin monomers converted from fibrinogen with thrombin which are contained in the soluble trauma-healing hemostatic cellulose fiber including coagulation proteins, also promoting and activating a blood clot cascade even when the blood clot cascade is low or inactive; and

(3) Cross-linking reaction of the coagulation factor XIII which is contained in the same soluble trauma-healing hemostatic cellulose fiber stabilizes the agglutinates;

4. Furthermore, the inventive hemostatic fiber enhances adhesion and aggregation of blood platelets at the wound and interacts with fibronectin which is an adhesion protein, to promote cell adhesion activity of the fibronectin;

5. The advantages provided by the present invention have been substantiated by the comparative testing presented in the Tables and Figures of the present application. This comparative testing has been carried out under my direction and control;

6. Referring to the test results documented in the various Tables and Figures of the present application, Table 1 of the present application shows ability to control degree of hydroxyl group substitution in the hemostatic cellulose fiber, namely by controlling reaction time with monochloro acetic acid in accordance with the inventive method of preparation;

7. Table 2 of the specification shows complete solubility of the inventive hemostatic cellulose fiber in water and saline, whether the coagulation protein is imparted to the fiber by spraying or chemical bonding;

8. Referring to these comparative test results in Fig. 1, the improved fibrin monomer absorptivity was attained with the inventive hemostatic fiber having the coagulation protein either applied to the surface thereof or chemically bonded thereto (plots C and D), over hemostatic fiber having no coagulation protein imparted thereto (plot B) or the absence of hemostatic fiber altogether (plot A). Thus, the methods of application clearly result in a different improved hemostatic fiber being obtained;

9. Referring to Table 3 and Fig. 2, the improved platelet agglutination activity was attained with the inventive hemostatic fiber prepared by either method (graphs C and D) over hemostatic fiber containing no protein (graph B) or the absence of fiber altogether (graph A). In fact, fiber without the protein (graph B) failed to improve over total absence of fiber (graph A);

10. Table 4 shows the improved adhered cell count was also attained with the inventive fiber prepared according to either method over fiber containing no protein and the complete absence of fiber;

11. Test results presented in Table 5 show hemostasis can be achieved with the inventive fiber in as little as 10-11 seconds on average as opposed to fiber not containing protein (which took 33 seconds on average) or the absence of fiber altogether;

12. The improvements documented in the Tables and Examples of the present application are surprising and synergistic, not at all expected by the level of skill in the art available to me;

13. Soe et al., Colombo et al., Edwardson et al., and Sugitachi et al. fail to suggest to me, one skilled in the art, the features of the inventive hemostatic fiber and accompanying advantages which have been documented in the comparative testing, for the following reasons;

14. More particularly, Soe et al. disclose a tissue sealant comprising a combination of thrombin, fibrinogen, carboxymethylcellulose (CMC) or alkali metal or alkaline earth metal salt thereof which is prepared by admixing thrombin and CMC with fibrinogen (page 3, lines 30-35) or adding the CMC to a fibrinogen followed by adding a thrombin, or alternatively adding CMC to fibrin adhesive (page 4, lines 2-7). Examples 1 and 2 at page 5, lines 15-51 of Soe et al. describe preparing lyophilized CMC powder which is then added to a fibrin adhesive. Accordingly, Soe et al. fail to suggest to me, one skilled in the art, preparing a fiber for wound-healing benefit, much less a fiber imparted with coagulation protein in the fashion of the present invention;

15. Colombo et al. merely relate to etherification of cellulose fibers ultimately used in products such as sanitary towels or napkins, bandages, tampons, etc (column 7, lines 1-2). In fact, an explicit goal of Colombo et al. is preparing hydroinsoluble carboxy-alkyl cellulose (column 1, lines 43-48) for use in the sanitary towels, napkins, bandages, etc. which clearly should not be water-soluble. Accordingly, Colombo et al. actually teach away from making the present invention to me, one skilled in the art;

16. Edwardson et al. just contain a general disclosure that a thrombin-like enzyme can be immobilized upon a support such as cellulose or derivatives. Thus, Edwardson et al. neither disclose nor suggest to me, one skilled in the art, preparing an etherified cellulose fiber as in the claimed invention with the coagulation protein imparted in the inventive fashion to thereby attain the advantageous improvements documented in the present application;

17. Finally, Sugitachi et. al merely disclose fixing blood coagulation factor XIII to a variety of structures such as sutures, pads, bandages, etc. formed from a variety of materials, such as carboxymethycellulose (column 1, line 49- column 2, line 5). Sugitachi et al. neither disclose nor suggest preparing the claimed etherified cellulose fiber with all three coagulation proteins imparted thereto. Furthermore, the materials disclosed in Sugitachi et al. are not intended to be water or blood-soluble, hence teaching away from the

invention claimed herein to me, one skilled in the art;

18. Accordingly, even if Soe et al., Colombo et al., Edwardson et al., and Sugitachi et al. are combined, the features of the claimed invention together with the accompanying advantages would still not be suggested to me, one skilled in the art. The surprising synergistic advantages provided by the claimed invention have been documented in the extensive comparative testing presented in the present application; and

19. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and such willful false statement may jeopardize the validity of the application or any patent issued thereon.

May 26, 2004
Date

Yoshio Jo
Yoshio Jo

Notes from the Editor

We start out the year looking at Inherency, a Global Patent Language, Patenting and Ethics, and Copyright Term Limitation.

Irving Feit and Christina Warrick review the law on inherent anticipation in view of recent Federal Circuit cases and older decisions not previously understood as based on inherency.

Mike Meller proposes the adoption of a global patent language to control cost and facilitate substantive patent law harmonization.

R. Stephen Crespi explores the intersection of ethics and international patent law.

J.A. Lorengo mines the historical basis of the Patent and Copyright Clause to support his position on Copyright Term extension and *Eldred N. Ashcroft.*

Richard Stouffer summarizes the 30th Annual Rossman Award presentation.

Lastly, don't forget to check the Letter to the Editor.

That's all from here,
Louis S. Zarfas
Editor-in-Chief

Inherency in Patent Law

Irving N. Feit and Christina L. Warrick***

INTRODUCTION

A claim in a patent application lacks novelty if each element of the claim is disclosed in a single prior art reference.[1] In such a situation, the claim is said to be anticipated.

A prior art reference may anticipate a claim element by disclosing the element either expressly or inherently.[2] There are rarely any issues raised if all the elements are disclosed expressly in the reference.

Inherency relates to the anticipation of a claim by a prior art reference that does not expressly disclose at least one element of the claim. Such a reference may still be anticipatory if the missing element is inherent in the disclosure of the reference.[3]

Several recent Federal Circuit cases have clarified the law with respect to inherency. The present article will review some of these cases.

Two older cases that are generally not recognized, incorrectly in the opinion of the authors, as having been decided on the basis of inherency will also be reviewed. It will be proposed below that these cases were decided on the basis of inherency, and that they shed considerable light on the law of inherent anticipation.

Consideration of these and other relevant cases reveals three identifiable aspects of the doctrine of inherency. The first aspect is the

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1 35 USC 102.

2 See, for example, *Verdegaal Brothers v. Union Oil Co.*, 814 F.2d 628; 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

3 *Id.*

requirement for certainty. The second aspect is the chronological order used for determining whether inherency exists. The third aspect is the legal standard for determining whether inherency exists.

The Requirement for Certainty

It is well settled that one of the criteria for determining whether a claimed element is inherently disclosed in a prior art reference is certainty. As was stated by the Court of Customs and Patent Appeals (CCPA) more than sixty years ago:

> Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.[4]

A comparison between two cases illustrates the requirement for certainty. In *In re Zierden*,[5] an applicant discovered that deposits of alluvium in industrial waters could be removed and prevented by adding to such waters insoluble potassium metaphosphate and a solubilizing agent. Alluvium was described in the specification as "...silt, mud, and/or organic wastes and other accumulation which deposit on heat exchange surfaces and create problems of corrosion, loss of heat transfer efficiency, and the like..."[6]

Zierden's application was rejected by the patent examiner. The rejection was upheld by the Board of Appeals, now the Board of Patent Appeals and Interferences ("the Board"). Zierden appealed to the court responsible at the time for hearing patent appeals, namely the CCPA.[7]

The appealed claims were directed to both methods and compositions.[8] Claims 1 and 6 are representative:

4 *Hansgirg v. Kimmer*, 102 F.2d 212; 40 USPQ 665 (CCPA 1939). See also *In re Oelrich et al.*, 666 F.2d 578; 212 USPQ 323 (CCPA 1981).
5 411 F.2d 1325; 162 USPQ 102 (CCPA 1969).
6 *Id.* at 102.
7 *Id.*
8 *Id.* at 103.

1. The method of removing and preventing alluvium deposits in water systems which comprises adding to such systems insoluble potassium metaphosphate and a solubilizing agent therefor.

6. A composition for removing and preventing alluvium deposits in water systems consisting essentially of insoluble potassium metaphosphate, a solubilizing agent therefor and a compatible dispersing agent.

The patent examiner rejected both types of claims under 35 U.S.C. §103 as being obvious over French Patent No. 901765 in view of two secondary references. The French patent disclosed the use of insoluble potassium metaphosphate and a solubilizing agent to treat industrial heating and cooling water systems. The purpose of the treatment was to prevent calcium carbonate deposits known as scale. The secondary references were cited "primarily only to show that all industrial cooling waters contain deposit-forming sand, silt, mud, etc., which is considered to be the 'alluvium' recited."[9]

On appeal, the CCPA upheld the rejection of composition claim 6. The composition disclosed by the French patent and the composition recited in rejected claim 6 were found to be identical. The only difference was the substance intended to be removed from industrial waters with the composition.[10]

The court held that: "A mere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable."[11] Citing *In re Lemin*,[12] the court further reasoned that: "The directions on the label will not change the composition."[13] Therefore, the rejections of claims 6 was upheld.

A different result was achieved with regard to method claim 1. As was noted by the CCPA, there is statutory authority to grant a patent for a new use of a known process or composition of matter, as long as the claim to the new use satisfies the other provisions of the patent act.[14]

9 *Id.*
10 *Id.* at 104.
11 *Id.*
12 326 F.2d 437; 140 USPQ 273 (CCPA 1964).
13 *In re Zierden*, above, at 104.
14 *Id.*

The solicitor argued that:

...the secondary references make it clear that 'industrial waters' mentioned in the French patent as the subject of treatment to prevent scale, do contain alluvium and, this being so, the alluvium would *inherently* be removed.[15] (Emphasis added.)

The court rejected the solicitor's inherency argument. According to the court, the French patent disclosed the treatment of industrial waters only to prevent the deposition of scale.[16] Method claim 1 of the Zierden patent recited the treatment of industrial waters to prevent and remove alluvium deposits. Judge Rich, writing for the CCPA, observed that there is no teaching of removing alluvium from industrial waters in the French patent.[17]

Nor, in the court's opinion, was this deficiency of the French patent rectified by the secondary references. As mentioned above, the secondary references disclose that all industrial waters contain alluvium.

According to Judge Rich, all industrial waters do not necessarily contain alluvium at the time of carrying out the process described in the French patent. Thus, Judge Rich noted that the industrial waters treated in accordance with the French patent might have been filtered to remove alluvium before the addition of potassium metaphosphate to remove scale. Filtration to remove alluvium had, in fact, been taught in one of the secondary references.[18] Therefore, the rejection of method claim 1 was reversed.[19]

The solicitor, arguing for the patent office, had attempted to rely on *In re Tomlinson*[20] in support of his argument that method claim 1 of *Zierden* was inherently disclosed in the French patent.[21] The *Tomlinson* decision was also written by Judge Rich, and is factually closely related to *In re Zierden*. It is instructive to examine how Judge Rich distinguished the facts of the *Tomlinson* case from those in *Zierden*.

15 *Id* at 105.
16 *Id.*
17 *Id.*
18 *Id.*
19 *Id.* at 106.
20 363 F.2d 928; 150 USPQ 623 (CCPA 1966).
21 *In re Zierden*, above, at 106.

The claims at issue in *Tomlinson* stated the following:[22]

1. A light-stable composition comprising solid, isotactic, substantially crystalline polypropylene and a stabilizing quantity of (certain nickel dithiocarbamates).

18. A process of inhibiting degradation of polypropylene caused by exposure to light which comprises admixing solid, isotactic, substantially crystalline polypropylene and a stabilizing quantity of (certain nickel dithiocarbamates).

A prior art patent of Tholstrup et al. disclosed the stabilization of polypropylene against *heat* degradation by incorporating zinc dithiocarbamates.[23] The corresponding nickel dithiocarbamates were said to suffer serious disadvantage due to discoloration "...which militates against their use in producing the colorless products which are often much desired."[24]

According to Judge Rich, polypropylene containing nickel dithiocarbamates are specifically disclosed in the Tholstrup patent. Therefore, compositions comprising polypropylene and nickel dithiocarbamates, as recited in claim 1, were said to be expressly anticipated by the Tholstrup patent.[25]

The applicants in *Tomlinson* argued that the process of using nickel dithiocarbamates for stabilizing polypropylene against *ultraviolet light*, as recited in claim 18, was new.[26] As mentioned above, the Tholstrup patent disclosed the addition of nickel dithiocarbamates to polypropylene as being useful, although disadvantageous, for stabilizing the polypropylene against *heat* degradation.

Nevertheless, the CCPA affirmed the rejection of process claim 18. According to Judge Rich, the only step in the claimed process, namely admixing polypropylene and a nickel dithiocarbamate, was disclosed in the Tholstrup patent.[27]

Unlike its decision in *Zierden*, the CCPA did not consider the intended use in *Tomlinson* to constitute a patentable distinction of the claimed process over that of the prior art. Judge Rich explained as follows:

22 *In re Tomlinson*, above, at 625.
23 *Id.* at 624.
24 *Id.* at 628.
25 *Id.*
26 *Id.*
27 *Id.*

That (intended use) language ("inhibiting degradation of polypropylene caused by exposure to light"), in effect, states the *result* of admixing the two materials. While the references do not show a specific recognition of that result, its discovery by appellants is tantamount only to finding a property in the *old composition*, not in the nickel compound for which, it is argued, a new use has been found (original emphasis).[28]

Thus, Judge Rich in *Tomlinson* rejected the argument that light stabilization constituted a new use of the known process of admixing a nickel dithiocarbamate and polypropylene. Rather, light stabilization was said merely to constitute a property of the old mixture.[29]

Judge Rich in *Zierden*, by contrast, considered the removal of alluvium by potassium metaphosphate to constitute a new use of a known process. See above.

The distinction between a new use of a known process, as in *Zierden*, and a result of a known process, as in *Tomlinson*, is critical. The "new use" is patentable. The "result" is inherent and, therefore, unpatentable.

Why did Judge Rich find a new use in *Zierden* and merely an inherent result in *Tomlinson*? The authors believe the answer lies in the following distinction:

In *Zierden*, Judge Rich found it was known how to remove alluvium from industrial waters before carrying out the process described in the prior art cited against method claim 1.[30] Consequently, the prior art process did not necessarily always result in the claimed process.

In *Tomlinson*, however, Judge Rich explained that:

> ...it is of particular importance, we think, that no reference of record expressly discloses stabilizing polypropylene against the degradation effects caused by light.[31]

Accordingly, there was no disclosure in the prior art cited against Tomlinson teaching how to remove the light degradability of polypropylene before adding nickel dithiocarbamate to stabilize the polypropylene against heat degradation. Therefore, the property of light

28 *Id.*

29 *Id.*

30 As mentioned above, Judge Rich noted that a secondary reference disclosed filtration of industrial waters to remove alluvium.

31 *Id.* at 627.

degradability was always present, and could not be removed before carrying out the claimed process, as could the alluvium from industrial waters in *Zierden*. Thus, the prior art process of *Tomlinson* always, i.e., inherently, resulted in the claimed process.

As can be seen from the above, a composition claim is anticipated if the only difference between the claim and a reference that discloses the same composition is a statement of its intended use. In such a situation, e.g., claim 6 of *Zierden* and claim 1 of *Tomlinson*, it is the composition that is being claimed. If the same composition is in the prior art, the claim is anticipated.

Similarly, a process claim is inherently anticipated when the steps of the claimed process differ from the same steps disclosed in a prior art reference by the mere statement of a newly discovered, but inherent, result of the process. Thus, the demise of claim 18 in *In re Tomlinson*.

A process claim is not inherently anticipated, however, where, as in claim 1 of *Zierden*, a newly discovered use of the claimed process does not necessarily always result from the process disclosed in a prior art reference. Not even where the steps recited in the claims and those disclosed in the reference are identical.

Judge Rich's holdings in *Zierden* and *Tomlinson* provide a consistently predictable test for analyzing the certainty requirement necessary for establishing inherency. The test is absolute. For example, the requirement for certainty is not met when an allegedly inherent element of a claim is present in the prior art, but can theoretically be eliminated, as in *Zierden*.

It is interesting to note that *In re Zierden* and *In re Tomlinson* have not generally been cited in later inherency cases. Nevertheless, the later inherency cases are consistent with the *Zierden* and *Tomlinson* decisions, as will be shown below.

The reason for the relative obscurity of *Zierden* and *Tomlinson* may be that Judge Rich did not make it clear that these decisions were based on the principles of inherency. Nevertheless, both decisions are, in fact, clearly based on the principles of inherent anticipation.

Thus, in *Tomlinson*, the finding that stabilization against light as recited in Tomlinson's process claim constituted a previously unrecognized property in a known composition clearly means the property is inherent in the known composition. Moreover, Judge Rich in *Zierden* directly addressed the solicitor's argument that the prior art method of removing scale from industrial waters would inherently also remove alluvium, as recited in Zierden's claims. See above.

The authors believe, therefore, that *In re Zierden* and *In re Tomlinson* should be viewed as authoritative and important decisions based on the principles of inherency.

MEHL/Biophile International Corp. v. Milgraum[32] is a more recent case that addressed the requirement for certainty in order to establish inherency. The case involved the validity of U.S. Patent 5,059,192 to MEHL/Biophile. MEHL/Biophile sued Milgraum for patent infringement in the U.S. District Court for the District of New Jersey.

The patent relates to a method for removing hair. The method involves aligning a laser light applicator substantially vertically over a hair follicle opening. A pulse of laser energy having a wavelength readily absorbed by melanin in the hair follicle is applied. Absorption of the laser light heats the melanin. The heated melanin causes damage to the hair follicle, resulting in loss of hair.

The defendants relied on two references as allegedly anticipating the claims of the patent.[33] The first was a user manual for the RD-1200 laser ("Manual"). The Manual disclosed a method for removing tattoos by treating skin affected by tattoo ink with the laser.

The district court granted summary judgment to the defendant, Milgraum, holding the patent invalid in view of the Manual. MEHL/Biophile appealed to the Federal Circuit.[34]

According to the Federal Circuit, "...the Manual does not discuss hair follicles, let alone aligning the laser over a hair follicle opening."[35] The claimed invention, on the other hand, required a laser to be aligned substantially vertically over a hair follicle opening. Therefore, the claims were found not to be expressly anticipated by the Manual.[36]

The Federal Circuit then considered whether the Manual inherently anticipated the claims. According to the court, it was possible that the laser might be aligned substantially vertically over a hair follicle opening during the tattoo removal process taught by the Manual. The court noted, however, that inherency may not be based on possibilities, citing *Oelrich*, see above. Therefore, the court held that the Manual failed to

32 192 F.3d 1362; 52 USPQ2d 1303 (Fed. Cir. 1999).
33 *Id.* at 1305.
34 *Id.* at 1304.
35 *Id.* at 1306.
36 *Id.*

anticipate the patented claims inherently, and the district court's finding of summary judgment of patent invalidity with respect to the Manual was reversed.[37]

The second reference relied on by Milgraum to invalidate the patent of MEHL/Biophile was an article by Polla entitled "Melanosomes Are a Primary Target of Q-Switched Ruby Laser Irradiation in Guinea Pig Skin" ("Article"). The district court had not reached a decision on the merits based on the Article, since the court relied solely on the Manual for its grant of summary judgment to Milgraum.[38] Reversal of the district court decision required the Federal Circuit to consider Milgraum's argument that the MEHL/Biophile patent was inherently anticipated by the Article.

The Article describes an experiment in which collimated laser beams strike a circular aperture held in contact with the skin on the backs of guinea pigs. The purpose of the experiment was to define the nature and extent of pigmented cell injury.[39]

The Federal Circuit noted that the description of the experiment in the Article "...is replete with references to the irradiation of hair follicles and resulting follicular damage." Therefore, the court found that the experiment necessarily resulted in aligning the laser vertically over the hair follicle openings, as required by the claims.[40]

MEHL/Biophile argued that the Article failed to teach treating humans, and failed to teach hair removal. The Federal Circuit was not impressed with either argument.[41]

The Federal Circuit found that the claim was not limited to treating humans. Therefore, the failure of the Article to mention humans was found to be irrelevant.[42]

With regard to the argument that the Article failed to appreciate that the treatment resulted in hair removal, the court observed that it was undisputed that guinea pigs have hairy backs.[43] The court further reasoned that:

37 *Id.*
38 *Id.* at 1305.
39 *Id.* at 1306.
40 *Id.*
41 *Id.* at 1306-1307.
42 *Id.* at 1307.
43 *Id.*

the laser operating parameters disclosed in the article substantially coincide with those disclosed in the patent. Accordingly, to the extent the embodiment in the patent achieves hair depilation, so does the Polla method.[44]

The court noted the rule that: "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates."[45] Therefore, the Article was held to anticipate the claims inherently, and the judgment of invalidity of the patented claims was upheld.[46]

Chronological Test for Determining Inherency

The procedure for establishing whether a claim is expressly anticipated by a prior art reference is relatively simple. As was stated by the Federal Circuit: "Anticipation of a patent claim requires a finding that the claim at issue reads on a prior art reference."[47] Accordingly, one looks first to the claim to determine what the elements are, and then to the reference to determine whether each and every element is expressly disclosed therein.

The procedure for establishing inherent anticipation is more complex. One must still first look to the claims to determine what the elements are. If a claimed element is not expressly disclosed in the prior art, one must then determine whether the element is nevertheless inherently disclosed.

In order to determine whether a claimed element is inherently disclosed in a prior art reference, one might intuitively start with the claimed element, as one does to determine express inherency. One would then go backwards in time, and ask whether the claimed element is necessarily always found in the composition, or results in the process, disclosed in the reference. Such a procedure, referred to herein as the reverse chronology, would be analogous to the procedure used to establish express anticipation.

44 *Id.*
45 *Id.* at 1305, citing In re King, 801 F.2d 1324; 231 USPQ 136, 138 (Fed. Cir. 1986).
46 *Id.*
47 *Atlas Powder*, 190 F.3d 1342; 51 USPQ2d 1943, 1945 (Fed. Cir. 1999) citing *Titanium Metals v.*

In fact, the test for determining whether inherency exists is not the intuitive one. According to established case law, one looks first to the prior art disclosure, and then asks whether the prior art disclosure necessarily always results in the claimed invention. This chronological order is referred to herein as the forward chronology. The forward chronology has been articulated in various decisions of the CCPA and the Federal Circuit as follows:

> [I]f a previously patented device, in its normal and usual operation, will perform the function which an appellant claims in a subsequent application for process patent, then such application for process will be considered to have been anticipated by the former patented device.[48]

> If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught (in the reference) would result in the performance of the questioned function (claimed), it seems to be well settled that the disclosure should be regarded as sufficient.[49]

> Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates.[50]

> To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference ....[51] The Board made no attempt to show that the fastening mechanisms of (the prior art reference) that were used to attach the diaper to the wearer also necessarily disclosed the third separate fastening mechanism of claim 76.[52]

> The pertinent inquiry was whether the prior art inherently discloses the claimed (unknown) fuse-removal mechanism, not whether the fuse-removal mechanism is an inherent characteristic of the claimed (known) structure.[53]

48 *In re Ackenbach*, 45 F.2d 437, 439; 7 USPQ 268, 270 (CCPA 1930).
49 *In re Hansgirg v. Kimmer*, above at 667. *In re Oelrich*, above at 326.
50 *Atlas Powder*, above at 1946 citing *In re King*, above at 138. *MEHL/Biophile*, above at 1305, citing *In re King*, *id.* *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316; 58 USPQ2d 1545, 1552 (Fed. Cir. 2001), citing *MEHL/Biophile*, above.
51 *In re Robertson*, 169 F.3d 743; 49 USPQ2d 1949, 1950-1951, (Fed. Cir. 1999), citing *Continental Can Co. v. Monsanto Co.*, 948 F2d 1264; 20 USPQ2d 1746; 1749 (Fed. Cir. 1991).
52 *In re Robertson*, above at 1951.
53 *EMI Group North America v. Cypress Semiconductor*, 104 F. Supp. 2d 370 (D. Del. 2000); reversed on other grounds, see below. 268 F.3d 1342; 60 USPQ2d 1423 (Fed. Cir. 2001).

A case that illustrates the significance of using the forward rather than the reverse chronology is *Eli Lilly and Co. v. Barr Laboratories, Inc.*[54] In this case, Eli Lilly accused Barr and others of infringing claim 7 of U.S. Patent 4,626,549 ("the '549 patent"). Barr and the other defendants asserted that claim 7 of the '549 patent was invalid for double patenting over claim 1 of U.S. Patent 4,590,213 ("the '213 patent").

The most controversial aspect of the *Eli Lilly* decision was its double patenting holding. The present article, however, will focus on the inherency issue, upon which resolution of the double patenting issue depended.

The Federal Circuit in *Eli Lilly* explained that a claim in a later patent is invalid for double patenting over a claim in an earlier patent where there is no patentable distinction between the two claims. A later claim was said to lack patentable distinction over an earlier claim if the later claim is anticipated by, or is obvious over, the earlier claim. Therefore, the court must first construe each of the claims, and then analyze the differences.[55]

If the later claim is not patentably distinct, and the earlier patent constitutes prior art, the later claim is invalid under 35 U.S.C. §102 or §103. If the earlier patent does not constitute prior art, however, and the two patents are commonly owned,[56] double patenting applies.[57] In the double patenting situation, the earlier patent is analogous to prior art for purposes relevant to this article.

According to the Federal circuit, both claim 1 of the earlier '213 patent and claim 7 of the later '549 patent encompass administering fluoxetine hydrochloride (Prozac) to humans. The only substantive difference between the two claims is their respective intended use.[58] Claim 1 of the '213 patent is directed to a method for treating anxiety. Claim 7 of the '549 patent covers a method of blocking the uptake of serotonin by brain neurons.[59]

54 251 F3d. 955; 58 USPQ2d 1869 (Fed. Cir. 2001).

55 *Id.* at 1878.

56 If the two patents are not commonly owned, an interference is the appropriate remedy. 35 U.S.C. 135(a).

57 If the scope of the later claim is different from that of the earlier claim, the double patenting may be overcome by a terminal disclaimer.

58 *Id.* at 1879.

59 *Id.*

As a result of their different intended uses, claim 7 of the '549 patent could not be held expressly anticipated by claim 1 of the '213 patent. Therefore, the court considered whether claim 7 of the '549 patent (blocking serotonin uptake) was inherently anticipated by claim 1 of the '213 patent (treating anxiety).

The court found that "...serotonin uptake inhibition is a natural biological activity that occurs when fluoxetine hydrochloride (i.e. Prozac) is administered to an animal, such as a human, for any purpose, including the treatment of anxiety." The court noted, for example, that Eli Lilly had previously stated in a 10-K filing to the Securities and Exchange Commission "...that serotonin uptake inhibition is the 'process by which Prozac works.' "[60]

Therefore, serotonin uptake inhibition, the intended use of the method recited in claim 7 of the '549 patent, was said to be an inherent property in the administration of fluoxetine hydrochloride to treat anxiety,[61] the intended use of the method recited in claim 1 of the '213 patent. Accordingly, the court held claim 7 of the '549 patent invalid for double patenting over claim 1 of the '213 patent.[62]

Eli Lilly and all of the other inherency decisions described above are consistent with the forward chronology. As explained above, one starts with the prior art,[63] and goes forward in time by determining whether practice of the prior art necessarily always results in the claimed composition or process.

The chronology for determining whether a claimed element is inherently disclosed in a prior art reference can be critical. In the *Eli Lilly* decision, for example, the Federal Circuit used the generally accepted forward chronology to determine that practice of the method recited in claim 1 of the earlier '213 patent (treating anxiety with Prozac) necessarily always resulted in the method of claim 7 of the later '549 patent (inhibiting serotonin uptake). Therefore Eli Lilly's '549 patent was held to be invalid for double patenting under the doctrine of inherency.[64]

60 *Id.*

61 *Id.* at 1880

62 *Id.* at 1881.

63 Or with the earlier patent in a double patenting situation, such as in *Eli Lilly*. See above.

64 See above.

The authors are unaware of a court decision that relied on the reverse chronology described above to analyze inherency. Nevertheless, it is interesting to speculate whether the result in *Eli Lilly* would have been affected by using the reverse chronology, i.e. by asking whether practice of the method recited in claim 7 of the later '549 patent (inhibiting serotonin uptake with Prozac) necessarily always results in the method of claim 1 of the earlier '213 patent (treating anxiety).

In answering this question, it must be remembered that inherency cannot be based on probabilities or possibilities. Inherency requires absolute certainty. See above.

The issue in a reverse chronology analysis, then, would be whether it might be possible for the administration of Prozac to inhibit serotonin uptake, and not simultaneously to treat anxiety. If so, it cannot be said that inhibiting serotonin uptake necessarily always results in treating anxiety, and the absolute certainty requirement for establishing inherency[65] is not satisfied.

It appears that it is possible for the administration of Prozac to inhibit serotonin uptake, and not simultaneously to treat anxiety. For example, a patient might take Prozac and not have anxiety in the first place. Alternatively, and by analogy to the *Zierden* case,[66] a patient suffering from anxiety might first take another drug to treat the anxiety, and then take Prozac to inhibit serotonin uptake.

According to this "reverse chronology" analysis, therefore, inherency would not be found. Therefore, use of the reverse chronology procedure in *Eli Lilly* does not lead to the same inherency conclusion reached by the Federal Circuit using the forward chronology procedure.

Legal Standard for Determining Inherency

While the law with respect to inherency is generally well settled, one issue remains. The issue relates to the standard for determining whether a limitation is inherent in a disclosure.

In *Continental Can*, the Federal Circuit held that extrinsic evidence used to establish inherency "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, *and that it would be so recognized by persons of ordinary skill*" (emphasis

65 See the section entitled "The Requirement for Certainty" above.

66 See above at footnote 5.

added).[67] In *Atlas Powder*, on the other hand, the Federal Circuit held that: "Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art."[68]

The *Continental Can* rule and the *Atlas Powder* rule appear, at least on the surface, difficult to reconcile, a conclusion reached by Forbes.[69]

Ebert, on the other hand, thought the two lines of cases could be reconciled based on the nature of the claimed element that was missing from the prior art. According to Ebert, if the element missing from the prior art relates to "scientific understanding," the element need not appear in the prior art. Ebert reasons that: "One cannot patent 'scientific understanding' of that which already was being done."[70]

The apparent conflict over the standard for establishing inherency was addressed by the Federal Circuit for the first time in *EMI Group North America v. Cypress Semiconductor*.[71] The case involved two U.S. patents of EMI (collectively, the EMI patents). U.S. 4,935,801 (the '801 patent) claims a structure for a metallic fuse for a semiconductor chip. U.S. 4,826,785 (the '785 patent) claims a method for making the fuse. The '801 patent is a divisional of the application that led to the '785 patent. The claims to the structure in the '801 patent and the claims to the method in the '785 patent both specifically recite a speculative mechanism by which the fuse can be blown with a low power laser.[72]

According to the Federal Circuit, three prior art patents disclose a fuse for a semiconductor chip having the same structure as that recited in the claims of the EMI patents. The prior art patents were also said to disclose blowing the fuse with a low power laser, as well as a method of manufacturing the disclosed fuse.[73]

The only difference between the prior art and the claims of the EMI patents was said to be the presence in the claims of the speculative, and previously unrecognized, mechanism by which the fuse was caused to be blown in the presence of a low energy laser.[74]

67 *Continental Can*, above at 1749. See also *Robertson*, above at 1950-1951 and *Telemac*, above at 1553.

68 *Atlas Powder*, above at 1946-1947. See also *MEHL/Biophile*, above at 1306 citing *In re King*, above.

69 See "Inherency in U.S. Patent Law," *The John Marshall Law School, Center for Intellectual Property Law News Source*, Vol. *III*, No. 1, Page 17 (Winter, 2001).

70 See *Intellectual Property Today*, "Inherent Difficulties" Vol. 6, No. 11, (November 1999).

71 See above at footnote 53.

72 *Id.* at 1424.

73 *Id.* at 1428-1429.

74 *Id.* at 1427.

During trial in the District Court for the District of Delaware, the jury found the mechanism to be an inherent property of the fuse. *EMI*, above. The district court, however, granted EMI's motion for judgment as a matter of law that its asserted claims are not anticipated or obvious.[75]

The basis for the district court's granting of EMI's JMOL motion was insubstantial evidence of inherency. The district court relied on the rule quoted above from *Continental Can* that when using extrinsic evidence to establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, *and that it would be so recognized by persons of ordinary skill*" (emphasis added).[76] In other words, the district court held that Cypress Semiconductor could not establish inherency because the mechanism recited in the EMI claims was not "...recognized by persons of ordinary skill."

The Federal Circuit held that the district court improperly granted EMI's JMOL motion. Therefore, the district court's decision was reversed, and the jury's finding that the claims are invalid as anticipated and obvious was reinstated.[77]

According to the Federal Circuit:

> This requirement, that a person of ordinary skill in the art must recognize that the missing descriptive matter is necessarily present in the reference, may be sensible for claims that recite limitations of structure, compositions of matter, and method steps which could be inherently found in the prior art. Such recognition by one of ordinary skill may be important for establishing that the descriptive matter would inherently exist for every combination of a claim's limitation. (Citing *In re Oelrich*, above.) ...Theoretical mechanisms or rules of natural law that are recited in a claim, that themselves are not patentable, however, do not need to be recognized by one of ordinary skill in the art for a finding of inherency. A person of ordinary skill does not need to recognize that a method or structure behaves according to a law of nature in order to fully and effectively practice the method or structure (citing, e.g. *MEHL/Biophile*, above).[78]

75 *Id.* at 1429.
76 *Id.* at 1429, citing *Continental Can*, above, at 1268.
77 *Id.* at 1430.
78 *Id.* at 1429.

Writing for the Federal Circuit, Judge Rader explained that the prior art discloses fuses having structures identical to those recited in the claims. Moreover, according to Judge Rader, the prior art discloses blowing these fuses with the same low power lasers disclosed in the EMI patents. Accordingly, Judge Rader found the requisite substantial evidence for a reasonable jury to find inherency.[79]

The *EMI* decision appears to agree with Ebert, see above. Thus, the "theoretical mechanisms or rules of natural law" of the *EMI* decision can be considered equivalent to the "scientific understanding" of the Ebert article. The *EMI* decision is also consistent with the *Atlas Powder* rule ("Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art").

Despite all of this consistency, however, the panel that decided the *EMI* case did not have the authority to overrule the *Continental Can* case. Accordingly, the *Continental Can* rule still exists ("To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill").

The authors believe all of the cases described above, including *Atlas Powder*, *Continental Can*, and *EMI*, can be reconciled. The cases appear to be consistent with the proposition that the ultimate standard for determining whether a claimed element is inherent in the prior art is the objective understanding of a person having ordinary skill.

The authors propose that the apparent conflict relates only to the timing of the objective understanding. *Continental Can*, *Atlas Powder*, *Robertson*, *Telemac*, *MEHL/Biophile*, and *EMI*, as well as the cases cited therein, all appear to be consistent with a single standard. If a person having ordinary skill presented with the facts would understand that the prior art inherently discloses a claimed element, the element is anticipated. It is irrelevant whether the understanding was apparent at the time of filing the application in question (as in *Continental Can*, *Robertson* and *Telemac*), or first becomes apparent at a later time (as in *Atlas Powder* and *MEHL/Biophile*). The objective understanding may for example, first occur during trial.

79 *Id.* at 1430.